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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
Group Art Unit 3766



JUL 31 2006 In re

Patent Application of

Michael R.S. Hill

Application No. 10/716,810

Confirmation No.: 7000

Filed: November 19, 2003

Examiner: Carl Hernandez Layno

**"METHOD AND SYSTEM FOR SPINAL  
CORD STIMULATION PRIOR TO AND  
DURING A MEDICAL PROCEDURE"**

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 CFR §1.97(b)

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The Examiner's attention is directed to the references which are listed on the attached Forms PTO/SB/08A and PTO/SB/08B. Copies of the foreign and non-patent references are attached. Also enclosed is our check in the amount of \$180.00 for the fee in this matter.

Please charge any additional required fees or credit any overpayment to Deposit Account No. 13-3080.

Citation of these references is respectfully requested.

No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate.

Respectfully submitted,

*Raye Lynn Daugherty*  
Raye L. Daugherty  
Reg. No. 47,933

07/31/2006 RFEKADU1 00000026 10716810

01 FC:1806

180.00 OP

File No. 065071-9057-00

Michael Best & Friedrich LLP  
100 East Wisconsin Avenue, Suite 3300  
Milwaukee, Wisconsin 53202-4108  
414.271.6560

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> JUL 31 2006 (use as many sheets as necessary) Sheet 1 of 12		<b>Complete if Known</b>	
		Application Number	10/716,810
		Filing Date	November 19, 2003
		First named Inventor	Michael R.S. Hill
		Group Art Unit	3766
		Examiner name	Carl Hernandez Layno
		Attorney Docket Number	065071-9057-00

**U.S. Patent Documents**

Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
	3,614,995	Probert, et al.	10/26/1971
	3,804,098	Friedman	4/16/1974
	3,937,226	Funke	2/10/1976
	4,088,138	Diack, et al.	5/9/1978
	4,198,963	Barkalow, et al.	4/22/1979
	4,161,952	Kinney, et al.	7/24/1979
	4,176,660	Mylrea, et al.	12/4/1979
	4,303,075	Heilman et al.	12/1/1981
	4,304,239	Perlin	12/8/1981
	4,332,259	McCorkle, Jr.	6/1/1982
	4,351,330	Scarberry	9/28/1982
	4,354,497	Kahn	10/19/1982
	4,458,677	McCorkle, Jr.	7/10/1984
	4,548,203	Tacker, Jr. et al.	10/22/1985
	4,574,807	Hewson et al.	3/11/1986
	4,603,705	Speicher, et al.	8/5/1986
	4,640,298	Pless et al.	2/3/1987
	4,671,295	Abrams et al.	6/9/1987

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449/PTO		<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/716,810	
Sheet 2 of 12		Filing Date	November 19, 2003	
		First named Inventor	Michael R.S. Hill	
		Group Art Unit	3766	
		Examiner name	Carl Hernandz Layno	
		Attorney Docket Number	065071-9057-00	
<b>U.S. Patent Documents</b>				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		4,715,367	Crossley	12/29/1987
		4,722,347	Abrams	2/2/1988
		4,753,244	Landymore et al.	6/28/1988
		4,919,147	Reinhardt, et al.	4/24/1990
		4,928,688	Mower	5/29/1990
		4,929,688	Allen et al.	5/29/1990
		4,931,464	Grover et al.	6/5/1990
		4,952,586	Morris et al.	8/28/1990
		4,960,133	Hewson	10/2/1990
		5,003,991	Takayama, et al.	4/2/1991
		5,024,228	Goldstone et al.	6/18/1991
		5,025,807	Zabara	6/25/1991
		5,036,848	Hewson	8/6/1991
		5,050,600	Parks	9/24/1991
		5,052,390	Hewson	10/1/1991
		5,056,532	Hull et al.	10/15/1991
		5,117,822	Laghi	6/2/1992
		5,117,828	Metzger et al.	6/2/1992
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<b>U.S. Patent Documents</b>				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		5,125,406	Goldstone et al.	6/30/1992
		5,127,407	Tan	7/7/1992
		5,129,392	Bardy et al.	7/14/1992
		5,154,172	Terry, Jr., et al.	10/13/1992
		5,156,149	Hudrluk	10/20/1992
		5,156,151	Imran	10/20/1992
		5,174,289	Cohen	12/29/1992
		5,178,149	Imburgia, et al.	1/12/1993
		5,179,950	Stanislaw	1/19/1993
		5,179,952	Buinevicius et al.	1/19/1993
		5,186,170	Varrichio et al.	2/16/1993
		5,188,104	Wernicke et al.	2/23/1993
		5,205,285	Baker, Jr.	4/27/1993
		5,215,086	Terry, Jr. et al.	6/1/1993
		5,231,988	Wernicke et al.	8/3/1993
		5,235,980	Varrichio et al.	8/17/1993
		5,263,480	Wernicke et al.	12/14/1993
		5,265,603	Hudrluk	11/30/1993
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		<b>Attorney Docket Number</b>	065071-9057-00

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	5,265,623	Kroll, et al.	11/30/1993
	5,267,560	Cohen	12/7/1993
	5,269,303	Wernicke et al.	12/14/1993
	5,282,468	Klepinski	2/1/1994
	5,284,146	Czar et al.	2/8/1994
	5,299,569	Wernicke et al.	4/5/1994
	5,304,120	Crandell et al.	4/19/1994
	5,304,206	Baker, Jr. et al.	4/19/1994
	5,304,220	Maginot	4/19/1994
	5,330,515	Rutecki et al.	7/19/1994
	5,335,657	Terry, Jr. et al.	8/9/1994
	5,365,926	Desai	11/22/1994
	5,379,765	Kajiwara et al.	1/10/1995
	5,411,529	Hudrlík	5/2/1995
	5,417,713	Cohen	5/23/1995
	5,456,254	Pietroski et al.	10/10/1995
	5,476,485	Wieinberg, et al.	12/19/1995
	5,501,702	Plicchi et al.	3/26/1996

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Sheet 5 of 12		Attorney Docket Number	065071-9057-00
<b>U.S. Patent Documents</b>			
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document
		5,501,703	Holsheimer et al.
		5,514,161	Limousin
		5,540,730	Terry, Jr.
		5,571,150	Wernicke et al.
		5,584,867	Limousin
		5,611,350	John
		5,656,420	Chien
		5,662,689	Elsberry, et al.
		5,668,117	Shapiro
		5,674,259	Gray
		5,700,282	Zabara
		5,707,400	Terry, Jr., et al.
		5,713,924	Min et al.
		5,713,929	Hess et al.
		5,720,768	Verboven-Nelissen
		5,755,682	Knudson, et al.
		5,782,874	Loos
		5,791,187	Chang
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Sheet 6 of 12		<b>Filing Date</b>	November 19, 2003
		<b>First named Inventor</b>	Michael R.S. Hill
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<b>U.S. Patent Documents</b>			
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document
		5,792,203	Schroepel
		5,797,970	Pouvreau
		5,799,661	Boyd, et al.
		5,824,021	Rise
		5,836,994	Bourgeois
		5,840,076	Swanson et al.
		5,846,263	Peterson et al.
		5,846,264	Andersson, et al.
		5,874,420	Pelleg
		5,889,033	Kaminski
		5,893,882	Peterson et al.
		5,902,324	Thompson et al.
		5,928,272	Adkins, et al.
		5,964,789	Karsdon
		5,977,408	Levin et al.
		5,995,872	Bourgeois
		5,998,386	Feldman
		6,014,588	Fitz
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Sheet 7 of 12		First named Inventor	Michael R.S. Hill
		Group Art Unit	3766
		Examiner name	Carl Hernandez Layno
		Attorney Docket Number	065071-9057-00

**U.S. Patent Documents**

Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
	6,042,538	Puskas	3/28/2000
	6,043,273	Duhaylongsod	3/28/2000
	6,060,454	Duhaylongsod	5/9/2000
	6,073,048	Kieval, et al.	6/6/2000
	6,087,394	Duhaylongsod	7/11/2000
	6,091,988	Warman et al.	7/18/2000
	6,101,412	Duhaylongsod	8/8/2000
	6,103,722	Schultz, et al.	8/15/2000
	6,127,410	Duhaylongsod	10/3/2000
	6,141,589	Duhaylongsod	10/31/2000
	6,141,590	Renirie et al.	10/31/2000
	6,184,239	Puskas	2/6/2001
	6,185,459	Mehra et al.	2/6/2001
	6,221,851	Feldman	4/24/2001
	6,234,985	Lurie et al.	5/22/2001
	6,253,108	Rosborough, et al.	6/26/2001
	6,266,564	Hill et al.	7/24/2001
	6,272,380	Warman et al.	8/7/2001

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		<b>Attorney Docket Number</b>	065071-9057-00

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	6,299,564	Gessler et al.	10/9/2001
	6,303,293	Patterson et al.	10/16/2001
	6,304,777	Ben-Haim, et al.	10/16/2001
	6,381,499	Taylor et al.	4/30/2002
	6,414,018	Duhaylongsod	7/2/2002
	6,429,217	Puskas	8/6/2002
	6,442,429	Hill et al.	8/27/2002
	6,449,507	Hill et al.	9/10/2002
	6,473,644	Terry, Jr. et al.	10/29/2002
	6,479,523	Puskas	11/12/2002
	6,487,446	Hill et al.	11/26/2002
	6,532,388	Hill et al.	3/11/2003
	6,537,540	Burstein et al.	3/25/2003
	6,542,774	Hill et al.	4/1/2003
	6,554,781	Carter et al.	4/29/2003
	6,572,895	Smith et al.	6/3/2003
	6,587,719	Barrett et al.	7/1/2003
	6,589,954	Mavunkel et al.	7/8/2003

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	6,609,025	Barrett et al.	8/19/2003
	6,622,038	Barrett et al.	9/16/2003
	6,622,041	Terry, Jr. et al.	9/16/2003
	6,622,047	Barrett et al.	9/16/2003
	6,628,987	Hill et al.	9/30/2003
	6,656,960	Puskas	12/2/2003
	6,690,973	Hill et al.	2/10/2004
	6,711,436	Duhaylongsod	3/23/2004
	6,718,208	Hill et al.	4/6/2004
	6,721,603	Zabara et al.	4/13/2004
	6,735,471	Hill et al.	5/11/2004
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	6,778,854	Puskas	8/17/2004
	6,904,318	Hill et al.	6/7/2005
	6,912,419	Hill et al.	6/28/2005
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	2002/072782	Osorio, et al.	6/13/2002
	2002/0198570	Puskas	12/26/2002
	2002/0198571	Puskas	12/26/2002
	2003/045909	Gross et al.	3/6/2003
	2003/0074039	Puskas	4/17/2003
	2003/0216775	Hill et al.	11/20/2003
	2003/0216790	Hill et al.	11/20/2003
	2004/0024422	Hill et al.	2/5/2004
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	2005/0096707	Hill et al.	5/5/2005
	2005/0143412	Puskas	6/30/2005

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Examiner Initials	Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
	AU	9890156	Duhaylongsod	3/1/1999		
	AU	779255	Puskas	6/23/2000		
	CA	2,310,183	Puskas	8/26/1998		
	CA	2,376,903	Puskas	6/23/2000		
	DE	2811325	Hildebrandt et al.	9/27/1979		
	EP	0589252	Dreher	3/30/1994		
	EP	1005337	Puskas	6/7/2000		
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	EP	1181947	Borkan	2/27/2002	X	
	JP	2001505980	Puskas	6/23/2000		
	JP	200507363	Puskas	8/26/1998		
	MX	2043	Puskas	8/26/1998		
	WO	9740885	Jonkman et al.	2/5/1997		
	WO	9907354	Duhaylongsod	2/18/1999		
	WO	0100273	Puskas	2/4/2001		
	WO	0189526	Tracey et al.	11/29/2001		
	WO	9211064	Mehra	7/9/1992		
	WO	9900057	Ward	1/7/1999	X	
	WO	9909971	Puskas	3/4/1999		
	WO	9909973	Puskas	8/26/1998		
	WO	9963926	Lurie, et al.	12/16/1999	X	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/716,810
(use as many sheets as necessary)				Filing Date	November 19, 2003
Sheet 12 of 12				First named Inventor	Michael R.S. Hill
				Group Art Unit	3766
				Examiner name	Carl Hernandez Layno
				Attorney Docket Number	065071-9057-00

**U.S. Patent Documents**

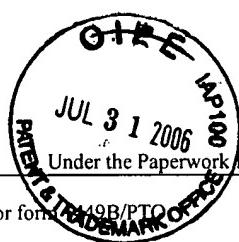
Examiner Initials		U.S. Patent Document Number		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	
	WO	0001306	Scher, et al.	1/13/2000	X	
	WO	0009206	Mehra, et al.	2/24/2000	X	
	WO	0226320	Hill, et al.	4/4/2002	X	

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet	1	of	9	Attorney Docket Number	065071-9057-00
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**Complete if Known**

Application Number	10/716,810
Filing Date	November 19, 2003
First Named Inventor	Michael R.S. Hill
Group Art Unit	3766
Examiner Name	Carl Hemandz Layno

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
		AGNEW, William F., et al., "Considerations for Safety with Chronically Implanted Nerve Electrodes, Epilepsia, 31(Suppl. 2), 1990, pp. S27-S32, Raven Press, Ltd., New York.
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Sheet	2	of	9	Application Number 10/716,810
				Filing Date November 19, 2003
				First Named Inventor Michael R.S. Hill
				Group Art Unit 3766
				Examiner Name Carl Hemandz Layno
				Attorney Docket Number 065071-9057-00

<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>		
Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
		BLUERMEL, K.M., et al., "Parasympathetic Postganglionic Pathways to the Sinoatrial Node," Am. Phys. Soc., 1990, pp. H1504-H1508.
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		Declaration/Clarification of John D. Puskas, MD., dated October 11, 2005, pp. 1-7.
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/716,810
				Filing Date	November 19, 2003
				First Named Inventor	Michael R.S. Hill
				Group Art Unit	3766
				Examiner Name	Carl Hemandz Layno
Sheet	3	of	9	Attorney Docket Number	065071-9057-00

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
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		DIPIRO, J., et al., "Pharmacotherapy: A Pathophysiologic Approach," p. 153-157, 1989.
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Sheet	4	of	9	Application Number 10/716,810
				Filing Date November 19, 2003
				First Named Inventor Michael R.S. Hill
				Group Art Unit 3766
				Examiner Name Carl Hemandz Layno
				Attorney Docket Number 065071-9057-00

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		GORMAN, Christine, et al., "How New Heart-Scanning Technology Could Save Your Life," <u>Time</u> , September 5, 2005, pp. 61 and 67.
		GUARINI, S., et al., "Efferent Vagal Fibre Stimulation Blunts Nuclear Factor -κB Activation and Protects Against Hypovolemic Hemorrhagic Shock, <u>Circulation</u> , 2003, Vol. 107, No. 8, pp. 1189-1194.
		GULICK, T., et al., "Interleukin 1 and Tumor Necrosis Factor Inhibit Cardiac Myocyte β-adrenergic Responsiveness," <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 86, pp. 6753-6757, Sept. 1989.
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Sheet	5	of	9	Application Number	10/716,810
				Filing Date	November 19, 2003
				First Named Inventor	Michael R.S. Hill
				Group Art Unit	3766
				Examiner Name	Carl Hemandz Layno
				Attorney Docket Number	065071-9057-00

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
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		LAGI, A., et al., "Age-Related Changes of Cardiac Parasympathetic Modulation After Vasovagal Syncope," The Am. Jour. Of Cardiology, Vol. 83, March 15, 1999, pp. 977-980.			
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Sheet	6	of	9	Application Number	10/716,810
				Filing Date	November 19, 2003
				First Named Inventor	Michael R.S. Hill
				Group Art Unit	3766
				Examiner Name	Carl Hemandz Layno
				Attorney Docket Number	065071-9057-00

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
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		MANN, D., "Mechanisms and Models in Heart Failure – A Combinatorial Approach," Circulation, Vol. 100, pp. 999-1008, 1999.
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		NOBREGA, et al., "Resting and Reflex Heart Rate Responses During Cholinergic Stimulation with Pyridostigmine in Humans," Braz. J. Med. Biol. Res. 1996, Nov: 29(11): 1461-5 (Abstract only)
		NOONAN, DAVID, "And the Beat Goes On," <u>Newsweek</u> , July 11, 2005, pp. 56-57.
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		PENRY, J. Kiffin, et al., "Prevention of Intractable Partial Seizures by Intermittent Vagal Stimulation in Humans: Preliminary Results," Epilepsia, 31(Suppl. 2), 1990, pp. S40-S43, Raven Press, Ltd., New York
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		RANDALL, Walter C., PhD., "Parasympathetic Control of the Heart," Chapter 4, Nervous Control of Cardiovascular Function, 1984, pp. 68-94.
		RANDALL, Walter C., Ph.D. et al., "Functional Anatomy of the Cardiac Efferent Innervation," Neurocardiology, 1988, pp. 3-24.
		REID, Steven A., "Surgical Technique for Implantation of the Neurocybernetic Prosthesis," Epilepsia, 31(Suppl. 2), 1990, pp. S38-S39, Raven Press, Ltd., New York
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		SATO, I., et al., "Age-Related Changes of Cardiac Control Function in Man," Jour. of Gerontology, 1981, Vol. 36, No. 5, pp. 564-572.

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		SEVERTSON, M., et al., "Vagal Nerve Monitoring: A Comparison of Techniques in a Canine Model," Am. Jour. of Otology, 18:398-400, 1997.
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		UTHMAN, Basim M., et al., "Efficacy and Safety of Vagus Nerve Stimulation in Patients with Complex Partial Seizures," Epilepsia, 31(Suppl. 2), 1990, pp. S44-S50, Raven Press, Ltd., New York.
		SUBRAMANIAN, V.A., "Clinical Experience with Minimally Invasive Reoperative Coronary Bypass Surgery," Eur. J Cardio-Thorac Surg, 1996, 10:1058-1062.

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Sheet	9	of	9	Application Number Filing Date First Named Inventor Group Art Unit Examiner Name
				10/716,810 November 19, 2003 Michael R.S. Hill 3766 Carl Hemandz Layno
				Attorney Docket Number 065071-9057-00

<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>		
Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
		WATKINS, L., et al., "Implications of Immune-to-Brain Communication for Sickness and Pain," Proc. Natl. Acad. Sci. USA, Vol. 96, pp. 7710-7713, July 1999.
		WESTABY, S., "Coronary Surgery Without Cardiopulmonary Bypass," British Hearth Journal, 73: 203-205.
		WILDER, B.J., et al., "Vagus Nerve Stimulation for the Control of Epilepsy," Proceedings of a Symposium held in conjunction with the American Epilepsy Society Annual Meeting, Boston, MA, December 2, 1989, Vol. 31, Supplement 2, 1990.
		WOODBURY, Dixon M., et al., "Effects of Vagal Stimulation on Experimentally Induced Seizures in Rats," Epilepsia, 31(Suppl. 2), 1990, pp. S7-S19, Raven Press, Ltd., New York
		YEH, Shing-Shing, et al., "Geriatric Cachexia: The Role of Cytokines <sup>1,2</sup> ," Am. J Clin. Nutr., Vol. 70, pp. 183-97, 1999.
		YOKOYAMA, T., et al., "Cellular Basis for the Negative Inotropic Effects of Tumor Necrosis Factor - $\alpha$ in the Adult Mammalian Heart," The Journal of Clinical Investigation, Vol. 92, pp. 2303-2312, Nov. 1993.
		YOKOYAMA, T., et al., "Tumor Necrosis Factor - $\alpha$ Provokes a Hypertrophic Growth Response in Adult Cardiac Myocytes," Circulation, Vol. 95, pp. 1247-1252, 1997.

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